

STU#:

INSTRUCTIONS:

- Depending on the nature of what you are doing, some sections may not be applicable to your research. If a section is not applicable, delete. You may delete subsections that are not applicable.
- Add the STU# from eIRB+ to the header of this document.
- Add the Version Date to the footer of this document.
- When you save and upload this document, add the protocol version date to the title.
- Keep an electronic copy of this document for your files. You will need to modify this copy when making changes.
- ***As you are creating this protocol, remove all instructions in italics and/or parentheses so that they are not contained in the final version of your protocol.***

PROTOCOL TITLE: *(Include the full protocol title.)*

PRINCIPAL INVESTIGATOR:

Name

Department

Telephone Number

Email Address

VERSION DATE:

(Include the version date here and in the footer.)

STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	
IND / IDE / HDE #	
Indicate Special Population(s)	<input type="checkbox"/> Children <input type="checkbox"/> Children who are wards of the state <input type="checkbox"/> Adults Unable to Consent <input type="checkbox"/> Cognitively Impaired Adults <input type="checkbox"/> Neonates of Uncertain Viability <input type="checkbox"/> Pregnant Women <input type="checkbox"/> Prisoners (or other detained/paroled individuals) <input type="checkbox"/> Students/Employees
Sample Size	
Funding Source	
Indicate the type of consent to be obtained	<input type="checkbox"/> Written <input type="checkbox"/> Verbal/Waiver of Documentation of Informed Consent <input type="checkbox"/> Waiver of HIPAA Authorization <input type="checkbox"/> Waiver/Alteration of Consent Process
Site	<input type="checkbox"/> Lead Site (For A Multiple Site Research Study) <input type="checkbox"/> Data Coordinating Center (DCC)
Research Related Radiation Exposure	<input type="checkbox"/> Yes <input type="checkbox"/> No
DSMB / DMC / IDMC	<input type="checkbox"/> Yes

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	<input type="checkbox"/> No
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OBJECTIVES:

(Describe the purpose, specific aims, or objectives. State the hypotheses to be tested.)

BACKGROUND:

(Describe the relevant prior experience and gaps in current knowledge.)

(Describe any relevant preliminary data.)

(Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.)

STUDY ENDPOINTS:

(Describe the primary and secondary study endpoints.)

(Describe any primary or secondary safety endpoints.)

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):

(Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.)

(Drug/Device Handling: If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on participants and be used only by authorized investigators.)

- If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

(If the drug is has an IND or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- Identify the holder of the IND/IDE/Abbreviated IDE.*
- Explain procedures followed to comply with sponsor requirements for FDA-regulated research.*

(Is this a NSR (Abbreviated IDE) Device?)

- If yes, provide rationale for your determination.*
- Identify where research procedures will be performed.*

PROCEDURES INVOLVED:

(Describe and explain the study design.)

(Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks.)

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- Procedures performed to lessen the probability or magnitude of risks.
- All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.
- The source records, including medical or educational records that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms.)

(What data will be collected during the study and how will that data be obtained?)

- If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.)

(For Humanitarian Use Device (HUD): provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.)

(If your study uses radiation, attach a [Radiation Dosimetry Form](#) in the Supporting Documents section of the application in eIRB+ and explain how much and how often radiation will be used.)

(Audio/Video Recording/Photography: If applicable, describe:

- the type of recording/photography being utilized
- why the type of recording is necessary to the research
- how the recordings/photograph(s) will be utilized in the research (e.g., data analysis only)
- how and where the recordings/photograph(s) are stored, who has access to them, and if/when they will be destroyed.)

DATA AND SPECIMEN BANKING

(If data or specimens will be banked for future use, describe

- where the specimens will be stored,
- how long they will be stored,
- how the specimens will be accessed,
- who will have access to the specimens, and
- the data to be stored or associated with each specimen.)

(Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.)

(If collecting and sharing genetic data, review the [checklist](#) and include the information addressed in the questions.)

SHARING RESULTS WITH PARTICIPANTS

(Describe if study results or individual participant results [such as results of investigational diagnostic tests, genetic tests, or incidental findings] will be shared with participants or anyone else (e.g., the participant's primary care physician).

(Describe how the results will be shared.)

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STUDY TIMELINES

(Describe:

- the duration of an individual's participation in the study,
- approximately how long it will take to enroll all study participants, and
- the estimated date for the investigators to complete this study's primary analyses.)

INCLUSION AND EXCLUSION CRITERIA

(Describe:

- how individuals will be screened for eligibility,
- the criteria that define who will be included or excluded in your final study sample,
- specify if you will include or exclude each of the following special populations (members of the populations below may not be included in your research unless you indicate this in your inclusion criteria):
 - Adults unable to consent
 - Individuals who are not yet adults (infants, children, teenagers)
 - Pregnant women
 - Prisoners
 - Vulnerable Populations
- If this study excludes certain populations, explain the rationale for the exclusion in detail.

VULNERABLE POPULATIONS

(If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare. Refer to the checklists below for specifics.)

["CHECKLIST: Pregnant Women \(HRP-412\)"](#)

["CHECKLIST: Neonates \(HRP-413\)"](#)

["CHECKLIST: Neonates of Uncertain Viability \(HRP-414\)"](#)

["CHECKLIST: Prisoners \(HRP-415\)"](#)

["CHECKLIST: Children \(HRP-416\)"](#)

["CHECKLIST: Cognitively Impaired Adults \(HRP-417\)"](#)

PARTICIPANT POPULATION(S)

Accrual Number:	Category/Group: (Adults/Children Special/Vulnerable Populations)	Consented: Maximum Number to be Consented or Reviewed/Collected/Screened	Enrolled: Number to Complete the Study or Needed to Address the Research Question
Local			
Study-wide			
Total:			

RECRUITMENT METHODS

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(Describe when, where, and how potential participants will be recruited.)

(Describe the source of participants.)

(Describe the methods that will be used to identify potential participants.)

(Describe materials that will be used to recruit participants. (Attach copies of these documents with the eIRB+ application. For advertisements, attach the final copy of printed advertisements.)

(When advertisements are taped for broadcast, attach the final audio/video file. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video file.)

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

(Describe the amount, timing, and method of any payments to participants. (e.g., gift card, ClinCard, check.)

(If payment is by check, you must request name, address and Social Security Number in order to issue a check for participation. Study payments are considered taxable income and are reportable to the IRS.)

(If payment is through the Shirley Ryan AbilityLab ClinCard, explain how much will be placed on the card at each visit.)

(If USDOD, then please be aware that compensation will need to check with their supervisor before they can accept any payment for participation in research.)

(If the investigator believes that the biologic specimens obtained could be part of or lead to the development of a commercial product, indicate if the participant will have any right to compensation or ownership interest related to such development.)

(Describe when and how participants will be informed of the results of the research.)

WITHDRAWAL OF PARTICIPANTS

(Describe:

- any anticipated circumstances under which participants will be withdrawn from the research without their consent,*
- any procedures for orderly termination,*
- procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.)*

RISKS TO PARTICIPANTS

(List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participant related to participation in the research. Include, for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks.)

(Consider physical, psychological, social, legal, and economic risks.)

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(If applicable, indicate:

- which procedures may have risks to the participants that are currently unforeseeable.*
- which procedures may have risks to an embryo or fetus should the participant be or become pregnant.*
- risks to others who are not participants.)*

POTENTIAL BENEFITS TO PARTICIPANTS

(Describe the potential benefits that individual participants may experience from taking part in the research. Include, for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.)

(Indicate if there is no direct benefit. Do not include benefits to society or others.)

DATA MANAGEMENT AND CONFIDENTIALITY

(Describe the data analysis plan, including any statistical procedures, power analysis, and a justification for your target enrollment number.)

(Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.)

(If applicable: refer to the [HRP-335 GDPR Data Protection Worksheet](#) for additional requirements if you are collecting data from participants in the European Economic Area).

(Describe any procedures that will be used for quality control of collected data.)

(Describe how data or specimens will be handled study-wide:

- What information will be included in that data or associated with the specimens?*
- Where and how data or specimens will be stored?*
- How long the data or specimens will be stored?*
- Who will have access to the data or specimens?*
- Who is responsible for receipt or transmission of the data or specimens?*
- How data or specimens will be transported?)*

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS

(This section is required when research involves more than Minimal Risk to participants.)

(Describe:

- The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing a data monitoring committee (DSMB/DMC/IDMC) and a plan for reporting data monitoring committee findings to the IRB and the sponsor.*
- The frequency of DSMB Meeting.*
- What data are reviewed, including safety data, untoward events, and efficacy data.*
- How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
- The frequency of data collection, including when safety data collection starts.*
- Who will review the data.*
- The frequency or periodicity of review of cumulative data.*

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- The statistical tests for analyzing the safety data to determine whether harm is occurring.
- Any conditions that trigger an immediate suspension of the research.)

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

(Describe the steps that will be taken to protect participants' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.)

(Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures.)

(Indicate how the research team is permitted to access any sources of information about the participants.)

COMPENSATION FOR RESEARCH-RELATED INJURY

(If the research involves more than Minimal Risk to participants, describe the available compensation in the event of research-related injury.)

(Provide a copy of contract language, if any, relevant to compensation for research-related injury.)

ECONOMIC BURDEN TO PARTICIPANTS

Describe any costs that participants may be responsible for because of participation in the research.

CONSENT PROCESS

(Indicate if you will be obtaining consent; and if so, describe:

- Where the consent process takes place.
- Any waiting period available between informing the prospective participant and obtaining the consent.
- Any process to ensure ongoing consent.
- The role of the individuals listed in the application as being involved in the consent process.
- The time that will be devoted to the consent discussion.
- Steps that will be taken to minimize the possibility of coercion or undue influence.
- Steps that will be taken to ensure the participants' understanding.)
- If applicable: If you will be obtaining consent from individuals in the European Economic Area refer to the [GDPR Guidance](#) for participant rights and for the two step process of consent including the use of the [GDPR Compliance Consent Document template \(HRP-590\)](#).

WAIVER OR ALTERATION OF CONSENT PROCESS (consent will not be obtained, required information will not be disclosed, or the research involves deception)

(Review the "[Waiver or Alteration of Consent Process](#)") to ensure you have provided sufficient information for the IRB to make these determinations.)

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(If the research involves a waiver the consent process for planned emergency research, review the [“Waiver of Consent for Emergency Research”](#) to ensure you have provided sufficient information for the IRB to make these determinations.)

- *Participants who are not yet adults (infants, children, teenagers)*
 - *Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)*
 - *For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “children.”*
 - *For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”*
 - *Describe whether parental permission will be obtained from:*
 - *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*
 - *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
 - *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.*
 - *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.*
 - *When assent of children is obtained describe whether and how it will be documented.*
- *Cognitively Impaired Adults*
 - *Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.*
- *Adults Unable to Consent*
 - *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
 - *For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “legally authorized representative.”*
 - *For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this*

- research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”
- Describe the process for assent of the adult participants. Indicate whether:
 - Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to assent and which will not.
 - If assent will not be obtained from some or all participants, an explanation of why not.
 - Describe whether assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents.
 - Humanitarian Use Devices
 - For HUD uses, provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.
 - Process to Document Consent in Writing
 - Describe how consent of the participant will be documented in writing.
 - If your research presents no more than minimal risk of harm to participants and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.
 - (If you will document consent in writing, please add this when prompted in your EIRB+ Application) If you will obtain consent, but not document consent in writing, attach a consent script. Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information. You may use “TEMPLATE CONSENT DOCUMENT (HRP-502)” to create the consent document or script.)
 - Setting
 - Describe the sites or locations where your research team will conduct the research.
 - If a Lead Coordinating Center or Data Coordinating center please see describe the role that NU has in this research study (for definitions please see below)
 - Describe the composition and involvement of any community advisory board.
 - For research conducted outside of the organization and its affiliates describe:
 - Site-specific regulations or customs affecting the research for research outside the organization.
 - Local scientific and ethical review structure outside the organization.
 - Lead Coordinating Center:
 - A lead coordinating center is defined as a site that provides the administrative, clinical, and technical expertise and leadership in the design and coordination of the multi-site collaborative research for a multi-center trial.
 - The principal investigator will be responsible for all site monitoring and for the coordination of participant recruitment, screening, enrollment and retention, data and safety monitoring, data collection and analysis, adherence to the protocol-directed procedures and guidelines, and the prompt review, reporting and resolution of adverse events.
 - Data Coordinating Center:
 - A data coordinating center is defined as a site that is responsible only for the collection and storage of data collected from all sites involved in a multi-site trial.

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PROTECTED HEALTH INFORMATION (PHI AND HIPAA)

(HIPAA applies to Protected Health Information (PHI). PHI is individually identifiable health information that is created or maintained by a covered entity (health care providers, hospitals, physician offices, health care clearing houses, health care plans), or their business associate(s).)

(If your research does not involve the use of medical record information maintained by a covered entity and if the information generated from research will not be placed into the medical record, then HIPAA does not apply.)

(Indicate the following:

- Does the study involve the creation, use, or disclosure of Protected Personal Health Information?*
- Will a HIPAA Authorization be obtained from for all or some participants?*
 - If HIPAA Authorization will not be obtained, indicate what alternatives will be used.*
- Names*
- Geographic Subdivisions: All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code and their equivalent geographical codes, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Bureau of the Census: (a) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people. (b) The initial three digits of a ZIP code for all geographic units containing 20,000 or fewer people are changes to 000.*
- Dates and Age: All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages of 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.*
- Telephone numbers*
- FAX numbers*
- Social Security Numbers*
- Medical Record Numbers*
- Health Plan Beneficiary Numbers*
- Account Numbers*
- Certificate/License Numbers*
- Vehicle Identifiers and Serial Numbers, including License Plate Numbers*
- Device Identifiers and Serial Numbers*
- Web Universal Resource Locators (URLs)*
- Internet Protocol (IP) Address Numbers*
- Biometric Identifiers, including Fingerprints and Voiceprints*
- Full-Face Photographic Images and any Comparable Images*
- Any other Unique Identifying Number, Characteristic, or Code, unless otherwise permitted by the Privacy Rule for re-identification)*

(Review Waiver of HIPAA Authorization and provide protocol specific justifications if HIPAA applies and you will not be obtaining a signed HIPAA Authorization.)

NON-ENGLISH SPEAKING PARTICIPANTS

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(Indicate what language(s) other than English are understood by prospective participants or representatives.)

(If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent.)

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE

(Describe the resources available to conduct the research: For example, as appropriate:

- Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period. For example, how many potential participants do you have access to? What percentage of those potential participants do you need to recruit?*
- Describe the time that you will devote to conducting and completing the research.*
- Describe your facilities.*
- Describe the availability of medical or psychological resources that participants might need as a result of anticipated consequences of the human research.*
- Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*
- Multi-Site Research (Complete if NU is the Lead Site and/or Data Coordinating Center)*
- Study-Wide Number of Participants*
- If this is a multicenter study, indicate the total number of participants to be accrued across all sites.)*

STUDY-WIDE RECRUITMENT METHODS

(If this is a multicenter study and participants will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.)

(Describe:

- when, where, and how potential participants will be recruited.*
- the methods that will be used to identify potential participants.*
- materials that will be used to recruit participants. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

(If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites. See "WORKSHEET: Communication and Responsibilities (HRP-830)." All sites have the most current version of the protocol, consent document, and HIPAA authorization.)

(All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record).

(All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.)

(All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.)

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(All local site investigators conduct the study in accordance with applicable federal regulations and local laws.)

(Indicate any location-specific regulations or customs affecting your project, including any local scientific and ethical review structure including if applicable, considerations of the General Data Protection Regulations (GDPR) for data collected in the European Economic Area applies (see [GDPR guidance](#)).

(All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.)

(Describe the method for communicating to engaged participating sites (see “WORKSHEET: Communication and Responsibilities (HRP-830)”):

- Problems (inclusive of reportable events).*
- Interim results.*
- The closure of a study)*

(If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See “WORKSHEET: Communication and Responsibilities (HRP-830).”)

- Where and how data or specimens will be stored locally?*
- How long the data or specimens will be stored locally?*
- Who will have access to the data or specimens locally?*
- Who is responsible for receipt or transmission of the data or specimens locally?*
- How data and specimens will be transported locally?)*